

## **DETAILED ACTION**

Applicant's arguments, filed 12/3/2010, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 1, 8-11, and 14-18 under 35 U.S.C. 103(a) as being unpatentable over US 6471993 ('993) in view of US 20060035350 ('350) is maintained.

Applicant argues that '993 and '350 do not disclose using the solid fat as a solvent according to claim 1. Claim 1 has been amended to include the limitation that the active ingredients, solid fat and optionally one or more surfactants are added into a reactor and melt-mixed homogenously.

Applicant's arguments have been fully considered but are not found persuasive.

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Regarding the limitation that the ingredients are melt-mixed homogenously, '993 teaches the need for the polymer, active ingredient, and porogen (solid fat), to be mixed homogenously (see Example 1). In the examples, use of a solvent such as methylene chloride is used to insure homogeneity, but the ordinary artisan would understand that melt mixing is an equivalent means of mixing the polymer, active ingredient, and porogen together to ensure homogeneity, and it would have been obvious to try to melt mix as an equivalent means of mixing the polymer, active ingredient, and porogen.

Regarding the limitation of claim 1 "...and solid fat as a solvent in an excess amount to the active ingredient", the porogen (solid fat) of '993 would be added in excess to the active ingredient, as the porogen is added in high concentration relative to the polymer scaffold (in Example 1, 800 mg of paraffin porogen are added to 200 mg PLGA). The amount of active ingredient added would be far less than the weight of PLGA, as the PLGA acts as a carrier for the active ingredient. Thus, as the amount of PLGA acting as a carrier would be greater than the amount of active ingredient, the amount of porogen would be even greater, as it is twice the amount of polymer.

### ***New Grounds of Rejection***

#### ***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 3-4 and 8-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase “rapidly cooling” is a relative term. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The rate of cooling is critical to the invention, as disclosed by the specification at page 13-14 states:

“In the solidification of the mixture by rapid cooling, it is preferred to rapidly decrease the temperature of the solution of the melted mixture to the temperature of 10 °C or less. When cooling is conducted slowly, crystal growth of the active ingredients may occur, and under such circumstances, the nanoparticles of the active ingredients are hardly achieved and the obtained particles are likely to have a broad particle distribution.”

“Rapidly cooling” is critical to the invention, however, it is unclear how rapid the cooling must be to be considered “rapidly cooling”. The claims and specification give no further guidance to what cooling rates are encompassed by the term, other than Examples 2-3, which teach an embodiment of “rapidly cooling”: “...the melted mixture was poured into a stainless steel plate which was precooled to 10 °C or less for rapid cooling and solidifying...”. As this is the only embodiment of “rapidly cooling” provided by the claims or specification, the Examiner recommends adding this language to the claims, that is, “... the melted mixture is rapidly cooled by pouring the mixture into a stainless steel plate which was precooled to 10 °C or less...”. Such language would be definite.

Claims 1, 3-4 and 8-20 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps in independent claims 1 and 4 are: "Wherein step (2) is performed at a temperature below the melting point of the solid fat." The specification at pages 17-18 discloses that the reactor temperature must be held below the melting point of the solid fat to prevent crystallization of the active agent and ensure formation of particles. If the temperature is too high, the solid fat will melt, and particles will not be formed. Thus, this limitation is an essential step in carrying out the invention to prepare nanoscale or amorphous particles.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/PAUL DICKINSON/  
Examiner, Art Unit 1618

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